

<b>INFORMATION DISCLOSURE CITATION</b> <b>Form PTO-1449 (Modified)</b> <i>(Use several sheets if necessary)</i>	<b>ATTY. DOCKET NO.</b> UCSF088CON	<b>SERIAL NO.</b> 10/622,283 KG 09/795,914
	<b>APPLICANT</b> Stern et al.	
	<b>FILING DATE</b> February 27, 2001	<b>GROUP</b> 1642

### U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
KG	AA 3,945,889	03/23/1976	Mima et al.			
KG	AB 5,427,779	06/27/1995	Elsner et al.			

### FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation
AC	WO 88/02261	04/07/88	PCT			Yes No
AD	WO 89/05329	06/15/89	PCT			
AE	WO 96/03497	02/08/96	PCT			

### OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

KG	AF	Afify et al., (1993) "Purification and Characterization of Human Serum Hyaluronidase" Arch. Biochem. Biophys. 305 (2):434-441.
	AG	Baumgartner et al., (1988) "Phase I Study in Chemoresistant Loco-regional Malignant Disease with Hyaluronidase" Reg. Cancer Treat. 1:55-58
	AH	Beckenlehner et al., (1992) "Hyaluronidase Enhances the Activity of Adriamycin in Breast Cancer Models in Vitro and in Vivo" J. Cancer Res. Oncol. 118:591-596.
	AI	Bonner et al., (1966) "Colorimetric Method for Determination of Serum Hyaluronidase Activity" Clinica Chimica Acta 13:746-752.
	AJ	Bordier, (1981) "Phase Separation of Integral Membrane Proteins in Triton X-114 Solution" J. Biol. Chem. 256(4):1604-1607.
	AK	Cashman et al., (1969) "The Hyaluronidase of Rat Skin" Arch. Biochem. Biophys. 135:387-395.
	AL	Czejka et al., (1990) "Influence of hyaluronidase on the blood plasma levels of 5-fluorouracil in patients." Pharmazie 45:H.9.
	AM	De Maeyer et al., (1992) "The Growth Rate of Two Transplantable Murine Tumors, 3LL Lung Carcinoma and B16F10 Melanoma, Is Influenced by Hyal-1, A Locus Determining Hyaluronidase Levels and Polymorphism" Int. J. Cancer 51:657-660.
KG	AN	De Salegui et al., (1967) "A Comparison of Serum and Testicular Hyaluronidase" Arch. Biochem. Biophys. 121:548-554.
	AO	Delpach et al., (1987) "An Indirect Enzyme-Immunoassay for Hyaluronidase" J. Immunol. Methods 104:223-229.
	AP	Doctor et al., (1983) "Isolation and Properties of a New Anticoagulant Protein from Commercial Bovine Testicular Hyaluronidase" Thrombosis Res. 30:565-571.

<b>EXAMINER</b> Karen G. Lipson	<b>DATE CONSIDERED</b> 8/25/04
<b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

INFORMATION DISCLOSURE CITATION Form PTO-1449 (Modified) (Use several sheets if necessary)		ATTY. DOCKET NO. UCSF088CON	SERIAL NO. 10/622,283 09/795,914
		APPLICANT Stern et al.	
		FILING DATE February 27, 2001	GROUP 1642
	AQ Dorfman et al., (1948) "A Turbidimetric Method for the Assay of Hyaluronidase" J. Biol. Chem. 172:367-375.		
KG	AR Fenger et al (1982) "Purification of Human Serum Hyaluronidase Using Chromatofocusing." (J. Chromatogr. 240:173-179)		
KG	AS Fiszler-Szafarz et al., (1989) "Hyal-1, a Locus Determining Serum Hyaluronidase Polymorphism, in Chromosome 9 in Mice" Somat. Cell. Mol. Genet. 15:79-83.		
	AT Fiszler-Szafarz et al., (1995) "Hyaluronidase in Human Somatic Tissues and Urine: Polymorphism and the Activity in Diseases." Acta Biochim Pol. 42:31-3.		
KG	AU Gabizon (1995) "Stealth Liposomes and Cancer Targeting: A Realistic Compromise in Drug Delivery." (J. Liposome Res., 5:704-710)		
	AV GenBank accession No. U03056, deposited Nov. 1, 1993.		
KG	AW Gregoriadis et al. (1993) "Liposomes in drug delivery. Clinical, diagnostic and ophthalmic potential." (Drugs, 45:15-28)		
	AX Cuntzenhoner et al., (1992) "A Substrate-Gel Assay for Hyaluronidase Activity" Matrix 12:388-396.		
	AY Harrison et al., (1988) "Multiple Forms of Ram and Bull Sperm Hyaluronidase Revealed by Using Monoclonal Antibodies" J. Reprod Fertil. 82:777-785.		
	AZ Hegi et al., (1994) "Allelotype Analysis of Mouse Lung Carcinomas Reveals Frequent Allelic Losses on Chromosome 4 and an Association between Allelic Imbalances on Chromosome 6 and K-ras Activation," Cancer Research 54, pp 6257-6264.		
	BA Horn et al., (1985) "Intravesical Chemotherapy of Superficial Bladder Tumors in a Controlled Trial with Cis-Platinum Versus Cis-Platinum Plus Hyaluronidase" J. Surg. Oncol. 28:304-307.		
KG	BB Johnstone et al. (1987) (Immunochimistry in Practice, Blackwell Scientific Publications, Oxford, pp. 30-31)		
	BC Kimata et al., (1983) "Increased Synthesis of Hyaluronic Acid by Mouse Mammary Carcinoma Cell Variants with High Metastatic Potential" Cancer Res. 43:1347-1354.		
	BD Kohno et al., (1994) "Effects of Hyaluronidase on Doxorubicin Penetration into Squamous Carcinoma Multicellular Tumor Spheroids and its Cell Lethality" J. Cancer Res. Clin. Oncol. 120:293-297.		
KG	BE Kolarova et al., (1970) "Host-Tumour Relationship XXIX. Hyaluronidase Activity and Seromucoid Concentration in Blood Serum of Patients with Cancer" Neoplasma 17:641-648.		
	BF Komender et al., (1973) "Isolation of Hyaluronidase from Kidney Extract," Bull. Acad. Pol. Sci. (Biol.) 21:637-41.		
	BG Kreil, (1995) "Hyaluronidases--A Group of Neglected Enzymes" Protein Sci. 4:1666-1669.		
	BH Levy et al., (1966) "Mammalian Glycosidases and Their Inhibition by Aldonolactones" Method Enzymol. 8:521-584.		
	BI Lien et al., (1990) "Collagen, Proteoglycan and Hyaluronidase Activity in Cultures from Normal and Scoliotic Chicken Fibroblasts" Biochim Biophys. Acta. 1034:318-325.		
	BJ Liu et al., (1996) "Expression of Hyaluronidase by Tumor Cells Induces Angiogenesis In Vivo" Proc. Natl. Acad. Sci. USA 93 (15):7832-7837.		
	BK Margolis et al., (1972) "The Hyaluronidase of Brain," J. Neurochem. 19:2325-32.		
KG	BL Natowicz et al., (1996) "Clinical and Biochemical Manifestations of Hyaluronidase Deficiency" N. Engl. J. Med. 335 (14):1029-1033.		

EXAMINER <i>Kay G. Gyles</i>	DATE CONSIDERED 3/25/04
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPBP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	09799-9T4 10/622783	
			Filing Date	February 27, 2001	
			First Named Inventor	STERN, ROBERT	
			Group Art Unit	1632	
Examiner Name	CHEN, LIPING				
Attorney Docket Number	UCSF-088CON				
Sheet	1	of	1		

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Foreign Patent Documents			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
KK		WO	96/31596	A1	Stern et al.	10-10-1996		

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>

Examiner Signature		Date Considered	12/9/05
-----------------------	--	--------------------	---------

<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard St. 18 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

<del>Notice of References Cited</del> 1449	Application/Control No. 09/795,914 10/622283	Applicant(s)/Patent Under Reexamination STERN ET AL.	
	Examiner Liping Chen	Art Unit 1632	Page 1 of 3

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Verma, I. M. et al. "Gene Therapy- promises, Problems and Prospects" (1997) Nature Vol. 389, pp. 239-242. <span>KG</span>
	V	Orkin, S. H. et al. "Report and Recommendations of The Panel to Assess The NIH Investment in Research on Gene Therapy" (1995) <span>KG</span>
	W	Eck, S. L. et al "Gene-Based therapy" in The Pharmacological Basis of therapeutics, Goodman & Gilman's, McGraq-Hill, Ninth Edition, pp. 77-101, 1996. <span>KG</span>
	X	Rozenberg, Y. et al. "Alternative Gene Delivery" S.T.P. Pharma Sci (2001) Vol. 11, pp. 21-30. <span>KG</span>

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<b>Notice of References Cited</b> 1449	Application/Control No. <del>00795,814</del> 10/622283	Applicant(s)/Patent Under Reexamination STERN ET AL.	
	Examiner Liping Chen	Art Unit 1632	Page 2 of 3

**U.S. PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

**FOREIGN PATENT DOCUMENTS**

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

**NON-PATENT DOCUMENTS**

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)			
	U	Nishikawa, M. et al. "Nonviral Vectors in The New Millennium: Delivery Barrier in Gene Transfer" (2001) Hum Gene Ther Vol. 12, pp. 861-870. <i>LB</i>			
	V	Balicki, D. et al. "Gene Therapy of Human Disease" (2002) Medicine Vol. 81, pp. 69-86. <i>LB</i>			
	W	Csoka, T. B. et al. "Hyaluronidases in Tissue Invasion" (1997) Invasion and Metastasis Vol. 17, No. 6, pp. 297-311. <i>LB</i>			
	X	Chang N. S. "Transforming Growth Factor-beta Protection of Cancer Cells Against Tumor Necrosis Factor Cytotoxicity is counteracted by Hyaluronidase" (1998) Int J Mol Med Vol. 2, No. 6, pp. 653-659. <i>LB</i>			

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<b>Notice of References Cited</b> 1449	Application/Control No. <del>09/705,914</del> 10/622283	Applicant(s)/Patent Under Reexamination STERN ET AL.	
	Examiner Liping Chen	Art Unit 1632	Page 3 of 3

#### U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

#### FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

#### NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)			
	U	Lepperdinger, G. et al. "Hyal2 - Less Active, But Nore Versatile?" (2001) Matrix Biol Vol. 20, pp. 509-514.			
	V				
	W				
	X				

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<del>Notice of References Cited</del> 1449	Application/Control No. 09/09,014 10/622283	Applicant(s)/Patent Under Reexamination STERN ET AL	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	Page 1 of 1

#### U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

#### FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

#### NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Lin Ji et al. Expression of several genes in the human chromosome 3p21.3 homozygous deletion region by an adenovirus vector results in tumor suppressor activities in Vitro and in Vivo. Cancer Res. 62:2715-2720, 2002. KB
	V	
	W	
	X	

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)  
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

11-21-05

PTO/SB/30 (09-04)

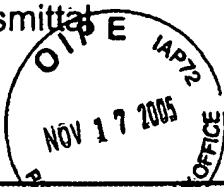
Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

# Request For Continued Examination (RCE) Transmittal

Address to:  
Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450



Application Number	10/622,283
Filing Date	July 18, 2003
First Named Inventor	STERN, ROBERT
Art Unit	1652
Examiner Name	GEBREYESUS, KAGNEW
Attorney Docket Number	UCSF-088CON2

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1. **Submission required under 37 C.F.R. § 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).

- a. ☐ Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- ii ☐ Consider the arguments in the Appeal Brief or Rely Brief previously filed on \_\_\_\_\_
- iii ☐ Other \_\_\_\_\_
- b. ☒ Enclosed
- i ☐ Amendment/Reply
- ii ☐ Affidavit(s)/Declaration(s)
- iii ☐ Information Disclosure Statement (IDS)
- iv. ☒ Other **Preliminary Amendment (16 pgs.); Exhibits 1-4**

## 2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(l) required)
- b. ☐ Other \_\_\_\_\_

## 3. Fees The RCE fee under 37 C.F.R. § 1.17 (e) is required by 37 C.F.R. § 1.114 when RCE is filed.

- a. ☒ The Director is hereby authorized to charge any underpayment or credit any overpayments associated with the following fees to Deposit Account No. **50-0815**.
- i ☒ RCE fee required under 37 C.F.R. § 1.17 (e)
- ii ☒ Extension of time fee (37 C.F.R. §§ 1.136 and 1.17)
- iii ☐ Other \_\_\_\_\_
- b. ☐ Check in the amount of \$ \_\_\_\_\_ enclosed
- c. ☒ **Payment by credit card** (Form PTO-2038 enclosed)

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Signature		Date	November 17, 2005
Name (Print/Type)	Paula A. Borden	Registration No.	42,344

EXPRESS MAIL NO. EV 687 633 835 US

This collection of information is required by 37 CFR 1.114. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

11/23/2005 CNGUYEN 00000048 10622283

01 FC:2801

395.00 OP